DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 15,2014

Cook Incorporated
Mr. Larry Pool
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K140593
Trade/Device Name: Advance® Salivary Balloon Catheter with Wire Guide
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: November 12, 2014
Received: November 13, 2014

Dear Mr. Pool:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140593

Device Name
Advance® Salivary Balloon Catheter with Wire Guide

Indications for Use *(Describe)*

The Advance® Salivary Balloon Catheter is intended for the dilation of lesions and strictures in the submandibular and parotid salivary ducts.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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5.0 510(k) SUMMARY

K140593
Advance® Salivary Balloon Catheter with Wire Guide
21 CFR §807.92
Date Prepared: December 12, 2014

Submitted By:

Applicant:	Cook Incorporated
Contact:	Larry D. Pool
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x102628
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	**Advance® Salivary Balloon Catheter with Wire Guide**
Common Name:	Endoscopes and accessories
Classification Name:	Laparoscope, General & Plastic Surgery
Regulation:	21 CFR §876.1500
Product Code:	GCJ

Predicate Devices:

- K072749 Sialo Dilatation Balloon Catheter (Sialo Technologies, Ltd.). The Sialo Balloon Dilatation Catheter is designed to allow dilatation of the salivary duct under endoscopic or radiological guidance. Dilatation can be therapeutic by itself (for duct strictures), or provide endoscopic access for stone removal.

- K122940 Advance Micro™ 14 Ultra Low-Profile PTA Balloon Catheter (Cook Incorporated). The Advance Micro™ 14 Ultra Low-Profile PTA Balloon Catheter is an over-the-wire balloon catheter indicated for vascular use.

- K011084 Mandrel Guidewires (Lake Region Manufacturing). The Mandrel Guidewires are a stainless steel core wire with a stainless steel coil tip indicated for diagnostic and interventional procedures.

Device Description:
The Advance® Salivary Balloon Catheter is an over-the-wire catheter available with an inflated balloon diameter of 1.5, 2.0, 2.5 and 3.0 millimeters in a balloon length of 2 centimeters. The catheter is available in an outer diameter of 2.5 French and in a length of 30 centimeters. Hydrophilic coating is applied to the distal 15 centimeters of the catheter shaft, which provides a lubricious surface when wetted. The balloon catheter is supplied with a 0.014 inch (0.36 millimeter) diameter stainless steel mandrel wire guide in a length of 50 centimeters. It is sterile and intended for one-time use.

Intended Use:
The Advance® Salivary Balloon Catheter is intended for the dilation of lesions and strictures in the submandibular and parotid salivary ducts.

Comparison to Predicates:
The Advance® Salivary Balloon Catheter with Wire Guide and the predicate device, the Sialo Dilatation Balloon Catheter (K072749), are substantially equivalent in that these devices have similar design and indications for use. Additionally, the proposed Advance Salivary Balloon Catheter with Wire Guide is identical in technological characteristics, materials, and methods of construction to the Advance Micro™ 14 Ultra Low-Profile PTA Balloon Catheter (K122940) and the Mandrel Guidewires (K011084) devices indicated for vascular use.

A comparison between the proposed and predicate devices is shown in the following table.

TABLE 1: Comparison of the proposed and predicate devices

Characteristic	Advance® Salivary Balloon Catheter with Wire Guide (This submission)	Sialo Balloon Dilatation Catheter (K072749)	Advance Micro™ 14 Ultra Low-Profile PTA Balloon Catheter (K122940)	Mandrel Guidewires (K011084)
Indications for Use	The Advance Salivary Balloon Catheter is intended for the dilation of lesions and strictures in the submandibular and parotid salivary ducts.	The Sialo device is a medical device for use by qualified surgeons in the treatment of salivary gland diseases.	The Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter is intended for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries including internal pudendal, iliac, renal; popliteal, femoral, iliofemoral, anterior tibial, posterior tibial, peroneal, pedal, radial, brachial, and ulnar, as well as obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary arteries.	To facilitate the placement of devices for diagnostic and interventional procedures.
Catheter OD (French)	2.5	Not available in 510(k) Summary	2.5	Not applicable
Catheter Length (cm)	30	Not available in 510(k) Summary	50, 90, and 150	Not applicable
Hydrophilic Coating	Yes	Not available in 510(k) Summary	Yes	Not applicable
Catheter Material	Polyimide/Polyurethane/ PTFE	Not available in 510(k) Summary	Polyimide/Polyurethane/ PTFE	Not applicable
Y-fitting Material	Polycarbonate	Not available in 510(k) Summary	Polycarbonate	Not applicable
Inflated Balloon OD (mm)	1.5, 2.0, 2.5, and 3.0	Not available in 510(k) Summary	1.5, 2.0, 2.5, and 3.0	Not applicable
Inflated Balloon Length (cm)	2.0	Not available in 510(k) Summary	2.0, 3.0, 4.0, 6.0, 8.0, 10.0 and 12.0	Not applicable
Balloon Material	Nylon	Not available in 510(k) Summary	Nylon	Not applicable
Maximum Balloon Pressure (atm)	16	16	16	Not applicable
Wire Guide OD (inch)	0.014	Not applicable	Not applicable	0.014 - 0.045
Wire Guide Length (cm)	50	Not applicable	Not applicable	20 - 500
Wire Guide Material	Stainless Steel	Not applicable	Not applicable	Stainless Steel

Technological Characteristics:

The following tests have been conducted to ensure reliable design and performance under the specified testing parameters. These tests include:

1. Bond Strength – Testing shows the tensile force during proper clinical use should not fracture or rupture the balloon catheter bonds. In conformance with the applicable sections of ISO 10555-1, the predetermined acceptance criteria were met.

2. Balloon Minimum Burst Strength – Testing shows the balloons will burst at or above the minimum rated burst pressure, with all failure modes being linear tears. The predetermined acceptance criterion was met.

3. Balloon Fatigue – Testing shows that balloons are free from leakage and damage on inflation after 10 cycles of inflation and deflation. The predetermined acceptance criteria were met.

4. Inflation and Deflation Time – Testing shows that the balloon will inflate to rated burst pressure within 60 seconds and fully deflate within 60 seconds. The predetermined acceptance criteria were met.

5. Resistance to Corrosion – Testing shows that after being subjected to a corrosive environment, the wire guide withstood a tensile force greater than or equal to 5 N. The predetermined acceptance criterion was met.

6. Visual and Dimensional Analysis – Testing shows that visually and dimensionally the wire guide and balloon catheter meet the design requirements. The predetermined acceptance criteria were met.

7. Simulated Use – Testing shows that the wire guide and balloon catheter shall pass through a simulated stricture and the force required to remove balloon catheter shall be less than 0.95 lbf. The predetermined acceptance criteria were met.

8. Balloon Working Length and Catheter Integrity – Testing shows that after the simulated use testing the catheter shall show no signs of damage and the balloon length shall be 2.0 centimeters $\pm$ 0.1 centimeter. The predetermined acceptance criteria were met.

9. Simulated Clinical Use – Testing shows that under a simulated clinical use with a human cadaver model, the balloon catheter shall have an atraumatic tip, must safely and reliably be introduced and track to the intended location, shall be compatible with the wire guide, shall be able to be removed from salivary duct and/or sheath, and location of the balloon catheter shall be verifiable within salivary duct. The predetermined acceptance criteria were met.

Human Factors Analysis:

An analysis of the critical tasks was performed for the proposed device in a Human Factors Analysis document in accordance with ISO 14971. The analysis identified no critical tasks which would or could result in serious harm.

Conclusion:

The results of these tests support a conclusion that the Advance® Salivary Balloon Catheter with Wire Guide met the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate devices, the Sialo Dilatation Balloon Catheter (Sialo Technologies, Ltd., K072749), the Advance Micro™ 14 Ultra Low-Profile PTA Balloon Catheter (Cook Incorporated, K122940), and the Mandrel Guidewires (K011084).